



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,459	05/31/2000	MERVYN JOSEPH FREDERICK	0/97322US	8345
6449	7590	12/20/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 12/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/555,459	Applicant(s) FREDERICK ET AL.	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Request of Continued Examination received on October 21, 2005 is acknowledged.

Claims **1-10** are pending in this application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/21/05 has been entered.

Claim Rejections - 35 USC § 112

The rejection of claims 5 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments of 10/21/05.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1616

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/02015 to Groenewegen et al in view of Cook et al (5,174,658).

Groenewegen et al teach a ring shaped device containing a medicament. See abstract. The device is preferably a vaginal ring used for hormonal replacement therapy or contraception. See abstract and page 2, lines 25-27. The reference teaches sterilizing the ring and packing it in a *usual manner* such as a placing the ring in a sachet consisting of a PET (12 microns), aluminum (9 microns), and LDPE (Low Density Polyethylene 40 microns) laminate. See page 5, lines 14-21. Note that PET is a type of polyester.

Groenewegen does not teach a resealable package with instant reclosing strip.

Cook et al teach a self-expanding and reclosable flexible pouch. See abstract. Cook teaches it is desirable to provide reclosable means when the bag contains certain products, many of which are not entirely consumed upon initial opening of the pouch, e.g., coffee, salted snacks, cleaning products, detergents, **pharmaceuticals**, etc. see column 1, lines 33-40. The pouch are used for containing such products as dry or powdered beverages, juices, dry soups, baking mixes, cooking oils, salted snacks, dry and instant cereals, and other food products; **medications**, cold remedies, mouthwash, baking mixes, laundry soaps and softeners, adhesives, paints and hard surface cleaners. See column 4, lines 4-15. Cook teaches the sidewalls of the pouch must be sufficiently thick and tough enough to resist punctures and leaks and are preferably selected from materials that can be easily handled, formed, and sealed together, preferably by heat-sealing. For

Art Unit: 1616

certain products, the sidewalls are made preferably made of a material or combination of materials that have certain characteristics such as absorption resistance, resistance to heat and cold, and resistance to light, air, and moisture. See column 6, lines 45-60. The barrier films taught include polyesters, polyethylene, polypropylenes, ethylene vinyl alcohol, and mixtures. See claim 4. Cook teaches the pouch comprises male and female securement means secured to extensible stays (adhesive to seal the securement means to the pouch) permits the pouch to be closed after initial opening. The extensible stays and male and female securement means are from low-density polyethylene (LDPE) or high-density polyethylene (HDPE). See abstract and column 7, lines 15-21.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Groenewegen and Cook et al and utilize a reclosing means. One would have been motivated to utilize a resealable closure means to package Groenewegen's medicated rings if one desired to package a plurality of vaginal rings and provide a means for storing the unused remainder for later use as taught by Cook.

With regard to the instant recitation that the package prevents the leakage of the active substance, it is the examiner's position that Groenewegen's package provides this functional limitation since the prior art teaches the criticality in packaging the ring in a sterile package and Groenewegen teaches the instant laminate (PET/aluminum/LDP) with the instant claimed thickness. Thus, although Groenewegen does not specify the functional properties of the package, it is the examiner's position that it provides an aseptic package that prevents the influence of the environment on the ring. Further, Cook teaches materials such as polyesters,

Art Unit: 1616

polyethylenes, and polypropylenes are materials that are resistant to light, air, moisture, cold, and heat; thus it is clear that Groenewegen's package would not leak.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/02015 to Groenewegen et al in view of JP 7-223653 in further view of Simonsen (5,711,609).

Groenewegen et al teach a ring shaped device containing a medicament. See abstract. The device is preferably a vaginal ring used for hormonal replacement therapy or contraception. See abstract and page 2, lines 25-27. The reference teaches sterilizing the ring and packing it in a *usual manner* such as a placing the ring in a sachet consisting of a PET (12 microns), aluminum (9 microns), and LDPE (Low Density Polyethylene 40 microns) laminate. See page 5, lines 14-21. Note that PET is a type of polyester.

Groenewegen does not teach a resealable package with instant reclosing strip or the material the reclosing means is made of.

JP teaches a laminated packaging bag comprising a seal that surrounds the bag and a sliding clasp fastener, a chuck, or a zipper across (reads on rib-groove means). See abstract, see page 2 [0006], and page 5, [0024]. The packaging material is utilized for various products including, drugs, toiletries, cosmetics, chemicals, foods, etc. See 1 of translated document. The package maintains the shelf life and stability of package contents. See page 1. Further, the package prevents the package from leaking and maintains air tightness. See page 2, second paragraph. The aluminum layer provides the airtight feature. See abstract.

JP teaches a laminated bag for chemicals, toiletries, and cosmetics includes for example laminated layers (outside to inside) of 1) polyesters layer/polyethylene layer or 2) **polyester**

Art Unit: 1616

layer/aluminum layer/ polyethylene layer. See [0017]. The thickness of the whole layered product is about 50-300 micrometers and especially 70-150 micrometers. See page 4 of translation. JP teaches the use of polyester as one of the materials for making the laminates. JP teaches the packing provides a closing motion of the bag that is easy and convenient. The zip has an engagement projection and an engagement crevice. See page 5.

JP does not teach the material in which the reclosing means is made of.

Simonsen teaches a child resistant package that comprises a flexible reclosable package. See abstract. Simonsen teaches reclosable packages provide a package that is easy to use, provides a less bulky method of storing unused drugs, and will not be damaged. See column 1, lines 10-60. The flexible reclosable package comprises a male closure profile and a female closure profile that are attached at the inner surfaces of two opposing films. See Figure 2. The male closure profile has a protruding male member while the female closure profile includes a pair of locking members forming a groove for receiving the male member. When pressure is applied to the male and female closure profiles, they engage and form a reclosable sealable mechanism (note this reads on rib and groove mechanism). See column 1, lines 45-65. The closure profiles are made of conventional materials such as polyethylene, polypropylene, or a blend of polyethylene and ethylene vinyl acetate. Simonsen teaches the use of LDPE (low density polyethylene) for making the closure profile since it provides significant savings in manufacturing costs. See column 3, lines 45-60. The package films may be composed of two or more layers of material. If the films are composed of multiple layers, the inner layer may be composed of a sealant material such as low-density polyethylene or low-density polyethylene blended with ethylene vinyl acetate. The outer layer may be composed of one or more barrier

Art Unit: 1616

materials characterized by higher toughness, stiffness, and heat resistance as compared to the inner layer. Examples of materials which may be incorporated in the outer layer include polypropylene, polyester, nylon, SURLYN, and polyethylene terephthalates (PET). See column 3, line 45 to column 4, line 10.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Groenewegen and JP and utilize a reclosing means. One would have been motivated to utilize a resealable closure means to package Groenewegen's medicated rings if one desired to package a plurality of vaginal rings and provide a means for storing the unused remainder for later use.

Further, it would have been obvious for one of ordinary skill in the art at the time the invention was made to further look at Simonsen et al and utilize the instant material of low density polyethylene for the closure means since Simonsen teaches LDPE is a low costing resin that saves in manufacturing cost. Additionally, Simonsen teaches the advantages of using a reclosing bag such as 1) providing a less bulking storage means for the unused portion of the drug, 2) it is easy to use, and 3) it is child resistance.

With regard to the instant recitation that the package prevents the leakage of the active substance, it is the examiner's position that Groenewegen's package provides this functional limitation since the prior art teaches the criticality in packaging the ring in a sterile package and Groenewegen teaches the instant laminate (PET/aluminum/LDP) with the instant claimed thickness. Thus, although Groenewegen does not specify the functional properties of the package, it is the examiner's position that it provides an aseptic package that prevents the influence of the environment on the ring.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection. However, the examiner has retained JP 7-223653 and Groenewegen to reject the claims, the merits of the references will be discussed.

Applicant argues that JP teaches a bag that Groenewegen does not teach a reclosable strip and JP does not cure this deficiency since JP teaches a bag with at least 4 layers. Applicant argues that JP teaches a bag that is used for cosmetics, medical products, compresses, and ointments but does not teach a vaginal ring. Applicant argues that JP does not relate to the problem of leakage of active substances from the ring to the environments and relates to a different problem such as providing air tightness and preventing leakage of odors. Applicant argues here is no motivation to combine the references absent impermissible hindsight.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it should be noted that the claim 1 is directed to a package not the medicate ring as argued. The method claims are drawn to packaging a medicated ring. The examiner points out that Groenewegen teaches the instant laminate, i.e. PET/aluminum/LDP with the instant claimed thickness enclosing a medicated ring. The only teachings deficient in Groenewegen is the reclosing means. The examiner points out that Groenewegen itself meets the limitation of the "consisting of" language by teaching the sachet has three layers. Thus, it is the examiner's position that Groenewegen itself teaches the functional limitations of "preventing leakage of the active substances into the environment". The examiner relies on JP for the reclosing means only. Thus, the fact that JP does not teach a medicated vaginal ring is moot since the primary reference is not deficient in this sense and the fact that teaches more than three layers is moot. However

Art Unit: 1616

for arguendo sake, the examiner points out that JP teaches a laminated bag for chemicals, toiletries, and cosmetics wherein the laminated layers include, for example, polyester layer/aluminum layer/ polyethylene layer (outside to inside) [0017].

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In instant case, the motivation to combine the references is that if one desired to package a plurality of vaginal rings and provide a means for storing the unused remainder for later use; thus one would have been motivated to incorporate the teachings of JP, wherein JP teaches a substantially similar package. It is the examiner's position that the motivation is within the level of one of ordinary skill in the art. Moreover, the motivation is further provided by the prior art, Simonsen, who also teaches that reclosable packages provides a storage means for unused portion of medicaments.

Thus, the instant invention is considered to be prima facie obvious.

Conclusion

All the claims are rejected at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

